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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,278	09/26/2000	Janet M. Hock	X-11965	5427

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EXAMINER

LI, RUIXIANG

ART UNIT PAPER NUMBER

1646

DATE MAILED: 07/23/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application N .

09/647,278

Applicant(s)

HOCK, JANET M.

Examiner

Ruixiang Li

Art Unit

1646

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 03 July 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 35,65 and 66.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 3. Applicant's reply has overcome the following rejection(s): Applicants' cancellation of claims 59-63 has made the rejection of claims 59-63 under 35 USC 112, first paragraph (Written Description) moot.

Applicants' cancellation of claims 56-58 and 64 has made the rejection of claims 56-58 and 64 under 35 USC 102 (b) as being anticipated by Neer et al. moot.

Applicants' cancellation of claims 59-62 has made the objection of claims 59-62 for minor informalities moot.


The objection of claim 35 for minor informalities has been withdrawn in view of Applicants' amendment to the claim.

Continuation of 5. does NOT place the application in condition for allowance because: The rejection of amended claims 35, 65, and 66 under 35 U.S.C. 102(b) as being anticipated by Neer et al. (U.S. Patent No. 4,698,328, October 1987) set forth in Paper No. 14 remains. Applicants continue to argue that the reference of Neer et al. does not anticipate the currently claimed invention because the cited reference does not teach reducing the risk of vertebral and non-vertebral bone fracture by the PTH (1-34) treatment and does not teach the specific dosage used in the method of treatment. Applicants' argument has been fully considered, but is not deemed to be persuasive for the reasons of record in Paper No. 14.

The Examiner further notes that Neer et al. teach a method for the treatment of osteoporosis in the same patient population comprising administering human PTH (1-34) in a daily dose of 100-700 units. Since Neer et al. teach treatment of osteoporosis, Neer et al. inherently teach reducing the risk of bone fracture because the definition of "osteoporosis" is defined as "reduction in the quantity of bone or atrophy of skeletal tissue; an age-related disorder characterized by decreased bone mass and increased susceptibility to fractures" (Stedman's Medical Dictionary 27<sup>th</sup> Edition).

The Examiner's position is evidenced by the prior art of record. For example, Lindsay et al. (The Lancet, 350:550-555, 1997) teach that treatment of postmenopausal women with osteoporosis with hPTH (1-34) in a daily dosage of 25 ug increased total-body bone mineral and that the increased vertebral mass was associated with a reduced rate of vertebral fracture. Lindsay et al. further teach that bone-mass changes may be consistent with a reduction in all osteoporotic fractures (page 550, right column). Cosman et al. teach that hPTH (1-34) increases bone mass and perhaps a reduction in osteoporotic fracture (Abstract). Hirano et al. teach that hPTH (1-34) enhances the mechanical strength of cortical bone in rabbits (abstract). Furthermore, Turner et al. teach hPTH (-34) induces parallel increases in bone mass and bone strength in animals, which is clearly cited in the article of N Engl J Med 344:1434-1441, 2001. One of the inventors, Gregory A. Gaich, is also a co-author of the article.

The daily dosage in units can be readily converted to the daily dosage in ug because the conversion factors can be readily obtained from the prior art. The article of Neer et al. (N Engl J Med 344:1434-1441, 2001; post filing date of the instant application) teaches the use of the daily dosage of 20 ug PTH (1-34) for treatment of osteoporosis and reduction of bone fracture in postmenopausal woman with osteoporosis, further supporting the Examiner position.

  
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